REMARKS

Entry of the foregoing amendments, reconsideration and reexamination of the subject application, as amended, pursuant to and consistent with 37 C.F.R. §1.112, and in light of the remarks which follow are respectfully requested.

By the present amendments, new claims are submitted in favor of the previous rejected claims without prejudice. While it is believed that it would be readily apparent to an ordinary skilled artisan, based on a reasonable interpretation of the as-filed disclosure, that the present invention embraces methods of producing de-differentiated or reprogrammed somatic cells which does not require the production of an embryo, in an effort to expedite prosecution, the claims have been rewritten to delete such verbiage.

Specific support for all of the claims may be found in the original claims as well as the text of the application at pages 4-6, and 11-13 et seq. Essentially, Applicants want to emphasize the fact that in contrast to prior nuclear transfer cloning materials wherein cloned embryos are produced by transplanting or fusing a somatic cell or somatic cell nucleus with an oocyte, which oocyte is enucleated before or after transplantation, thereby producing a NT embryo or NT fusion, the present invention instead reprograms a somatic cell or somatic cell nucleus by a method comprising contacting said somatic cell or somatic cell nucleus with a cytoplasmic extract derived from a cell which is less differentiated vis-à-vis said somatic cell, e.g. an oocyte, ES cell, blastomere or another embryonic cell type. In a

preferred embodiment, the reprogrammed cell will be used to produce ES cells (see page 12 et seq.). Thus, this is distinguishable from NT cloning materials that reprogram a somatic cell or somatic cell nucleus by transplanting or fusing with another cell, e.g. oocyte. Prior to the invention, the use of a cytoplasm or a cytoplasmic extract to effect reprogramming, in lieu of a nuclear transplantation into an enucleated cell was not contemplated as a viable means for somatic cell reprogramming.

Rebuttal To Claim Rejection Under 35 U.S.C. §112

The rejections are believed to be moot as the current claims do not recite that the introduction of cytoplasm "does not result in the production of an embryo." While it is maintained that this is clear from the as-filed specification, this phraseology does not appear in any of the current pending claims.

Rebuttal of §102 Rejection Based on Robl

US Patent Publication 2001/0012513 A1 does not anticipate the claimed invention. This published patent application, which is exclusively licensed to the assignee of the subject application, Advanced Cell Technology, Inc., describes methods whereby differentiated cells or nuclei thereof are reprogrammed by transplantation or fusion with another cell, e.g. an oocyte, which is enucleated. This fusion or transplantation process results in a NT embryo, which when cultured

under appropriate conditions can be used to derive different desired differentiated cell types.

By contrast, and a significant distinction therewith, the present invention does not fuse or transplant a somatic cell or somatic cell nucleus with another cell (enucleated oocyte) and produce a NT embryo. Rather, (and why the present invention does not produce an embryo) a somatic cell or somatic cell nucleus is reprogrammed or de-differentiated by juxtaposition or contacting with cytoplasm or a cytoplasm extract derived from cells which cells are less differentiated relative to said somatic cell. For example, the cytoplasm extract can be derived from an oocyte, a blastomere, an ES cell, or another embryonic cell type.

Rebuttal of 103 Rejection Based on Willadsen, Thomson, Greider and Robl

The use of cytoplasm or a cytoplasm extract as a cellular reprogramming means in lieu of cell fusion or transplantation is not disclosed or suggested by US 2001/0012513 A1 in view of Thomson (Science 282:1145-47 (1998)) and Greider et al. (WO 97/5967)).

For the reasons set forth above, the published Robl patent application does not anticipate or render obvious the use of cytoplasm or a cytoplasmic extract to reprogram or de-differentiate a somatic cell or somatic cell nucleus.

Neither does Thomson. Thomson rather teaches the use of IVF-produced human blastocysts to produce purported embryonic stem cell lines. There is no

mention of cytoplasm being used as a reprogramming medium to effect de-differentiation or reprogramming of somatic cells as in the present invention nor is this taught by Greider. Greider is cited based on its disclosure relating to producing transgenic animals and cells that express DNA constructs encoding telomerase. Likewise, this reference does not teach or suggest the programming or de-differentiation of a somatic cell or somatic cell nucleus by contacting same with cytoplasm or a cytoplasm extract from a less differentiated cell, which is of the same or different species relative to the somatic cell.

Rebuttal of §102 Rejection Based on Willadsen

Willadsen also does not teach or suggest the claimed invention. Rather, the reference teaches a method whereby while blastomeres are fused with enucleated or nucleated halves of unfertilized oocytes.

There is absolutely no teaching or suggestion relating to the use of cytoplasm to reprogram or de-differentiate a somatic cell or somatic cell nucleus as claimed.

Thus, Willadsen does not anticipate or render obvious the invention when considered alone or in combination with any of the afore-discussed secondary references.

Rebuttal of §102 Rejection Based on Wilmut et al.

Wilmut et al. describes a nucleic transfer cloning method whereby a somatic cell is fused with an enucleated fertilized egg and the resultant NT fusion is used to produce a cloned offspring. This is similarly no teaching relating to the use of cytoplasm or a cytoplasm extract (in lieu of an enucleated cell) to effect somatic cell or somatic cell nuclear reprogramming as claimed.

Rebuttal of §103 Rejection Based on Wilmut In View of Thomson In View of Greider et al.

None of the Wilmut, Thomson or Greider references teach or suggest to use of cytoplasm as a reprogramming medium to effect somatic cell or reprogramming. Rather, these references only respectively relate to nuclear transfer cloning methods whereby cells or nuclei are reprogrammed by the fusion or transplantation into an enucleated oocyte or the use of human blostoycte to produce ES cell lines that are engineered to express telomerase.

Therefore, the prior art references taken individually or in combination do not anticipate or make obvious the invention.

Conclusion

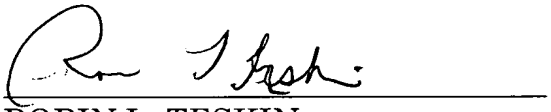
Based on the foregoing, the rejections set forth in the final rejection are not applicable against any of the pending claims as none teach or suggest the use of cytoplasm or a cytoplasmic extract as a reprogramming medium . Therefore, it is respectfully submitted that this application be permitted to proceed to allowance.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #100375/54405US).

Respectfully submitted,

October 23, 2003



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